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K963446

Exhibit 10

510(k) Summary

In accordance with section 513(l)(3) of the SMDA and as described in 21 CFR Part 807.92 interim rule dated April 28, 1992, this summary is submitted by:

Kendall Healthcare Products Company  
15 Hampshire Street  
Mansfield, MA 02048  
Date: August 28, 1996

1. Contact Person

David A. Olson, Regulatory Affairs  
Telephone: (508) 261-8530

2. Name of the Device

Classification Name: Hemodialysis System and Accessories

Common or Usual Name: Vascular Access Catheters

Proprietary Name: Kendall CURITY Dual Lumen Subclavian Catheters

3. Statement of Substantial Equivalence

The Kendall Dual Lumen Catheters are substantially equivalent in form, fit, function and intended use to the commercially available Neostar Dual Lumen Catheters, 510(k) No. K941851.

4. Description of Device

The Kendall Dual Lumen Catheters are single use, sterile devices. The single radiopaque cannula catheters have two distinct lumina which provide simultaneous "arterial" outflow and "venous" return. The catheters have two extension tubes, each with a color-coded in-line clamp (red for arterial outflow, blue for venous return) and luer lock adapter. The catheters are sold in 8.5, 10.0 and 11.0 Fr sizes.

5. Intended Use of the Device

The Kendall Dual Lumen Catheters are intended for use as short-term vascular access for hemodialysis. The catheters can be inserted in the femoral, subclavian or jugular vein as required.

6. Product Comparison

The Kendall Dual Lumen catheters are equivalent to the referenced predicate device in that they are the same design (single cannula, dual lumen), fabricated from similar materials and have equivalent indications for use.

7. Performance Data

**Non-Clinical Tests** - Comparative testing of the Kendall Dual Lumen Catheters with the predicate device found similar physical and functional properties. Such criteria included flow rate, hemolysis and recirculation studies. Biocompatibility testing of the catheter components has also been performed.

**Clinical Tests** - No clinical testing was performed.

**Test Conclusions** - Biocompatibility testing of the Kendall Dual Lumen Catheters has demonstrated that they contain no bioactive components. Comparative testing of the Kendall product and predicate device have found them similar in design, physical and functional attributes.